4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

Food and Drug Administration/Xavier University Global Medical Device Conference; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

The Food and Drug Administration (FDA) Cincinnati District, in cosponsorship with Xavier University, is announcing a public conference entitled "FDA/Xavier University Global Medical Device Conference (MedCon)." This 3-day public conference includes presentations from key FDA officials and industry experts with small group breakout sessions. The conference is intended for companies of all sizes and employees at all levels.

Dates and Times: The public conference will be held on May 6, 2015, from 8:30 a.m. to 5 p.m.; May 7, 2015, from 8:30 a.m. to 5 p.m.; and May 8, 2015, from 8:30 a.m. to 12:30 p.m.

Location: The public conference will be held on the campus of Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207, 513-745-3016.

Contact Persons: For information regarding this notice: Gina Brackett, Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513-679-2700, FAX: 513-679-2771, email: gina.brackett@fda.hhs.gov.

For information regarding the conference and registration: Mason Rick, Xavier University, 3800 Victory Pkwy., Cincinnati, OH 45207-5471, 513-745-3016, email: rickm@xavier.edu, or visit http://www.XavierMedCon.com.

Registration: There is a conference registration fee which covers the cost of the presentations, training materials, receptions, breakfasts, and lunches for the 3 days of the conference. Advanced registration begins February 6, 2015. Standard registration begins March 6, 2015. There will be onsite registration. The cost of registration is as follows:

Table 1.--Registration Fees[1]

Attendee Type	Advanced Rate (2/6/15 to 3/5/15)	Standard Rate (after 3/5/15)
Industry	$1,495	$1,695
Small Business (<100 Employees)	1,000	1,200
Startup Manufacturer	250	300
Academic	250	300
FDA/Government Employee	Free	Free

[1]The following forms of payment will be accepted: American Express, Visa, MasterCard, and company checks.

To register online for the public conference, please visit the "Registration" link on the conference Web site at http://www.XavierMedCon.com. FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the Federal Register.

To register by mail, please send your name, title, firm name, address, telephone, email, and payment information for the fee to Xavier University, Attention: Mason Rick, 3800 Victory Pkwy., Cincinnati, OH 45207-5471. An email will be sent confirming your registration.

Attendees are responsible for their own accommodations. The conference headquarters hotel is the Downtown Hilton Cincinnati Netherland Plaza, 35 West Fifth St., Cincinnati, OH 45202, 513-421-9100. Special conference block rates are available through April 16, 2015. To make reservations online, please visit the "Venue/Logistics" link at http://www.XavierMedCon.com.

If you need special accommodations due to a disability, please contact Mason Rick (see Contact Persons) at least 7 days in advance of the conference.

SUPPLEMENTARY INFORMATION: The public conference helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The conference will provide those engaged in FDA-regulated medical devices (for humans) with information on the following topics:

- Center Director Corner: Strategic Priorities for 2015 and Beyond
- Office of Compliance Strategic Priorities
- Advancements in Medical Device Software Technology
- Understanding and Preparing for the Revision of ISO13485
- Update from FDA's Office of Combination Products
- Unique Device Identification--Implementation
- FDA Inspections and Insights
- Understanding the Current Activities of the International Medical Device Regulators Forum
- European Union Medical Device/In Vitro Diagnostics Regulation Review
- Update from the Office of Device Evaluation
- Regulatory Submissions and Strategies
- Complaints, Corrective and Preventive Actions, and Recalls
- Regulatory Challenges in Asia
- Action Plan Writing
- Lunch Networking by Topic

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The conference helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization

Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The conference also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121) by providing outreach activities by Government agencies to small businesses.

Dated: February 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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